

GMP AUDIT CERTIFICATE

Rephine hereby certifies that a Good Manufacturing Practices (GMP) audit was completed at the company's facilities located at

Audit Date
March 13th, 2025

**Käserei Champignon
Hofmeister GmbH & Co. KG
Manufacturing Site:
ALPAVIT
Kemptener Straße 17 - 24,
87493 Lauben/Allgäu**

Regulatory frame

EU Directive **2001/83/EC** (and amendments 2004/27/EC and 2011/62/EU), 21 CFR 210 & 211 and UK Human Medicines Regulations 2012 (SI 2012/1916).

Reference to

The correspondent guidance **IPEC - PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients.**

The products in the audit scope encompassed
Excipients.

The audit was carried out following the rules and methodology set forth in Rephine's Quality System based on **ISO 9001 & ISO 17020**

The results of this audit are described in a full report, filed by Rephine. The report is available to the interested parties, and bound by the terms and conditions of confidentiality, agreed with the audited

Certificate Number
AUD-3513

Validity for
3 years

José C. Vergara
Technical Director

May 2025

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